

## **NOTICE OF INTENT**

### **Department of Insurance Office of the Commissioner**

#### **Regulation 122 — Roles and Responsibilities of Pharmacy Benefit Managers and Pharmacy Services Administrative Organizations**

(LAC 37:XIII.Chapter 185)

The Department of Insurance, pursuant to the authority of the Louisiana Insurance Code, R.S. 22:1 et seq., and in accordance with the Administrative Procedure Act, R.S. 49:950 et seq., hereby gives notice of its intent to promulgate Regulation 122 — Roles and Responsibilities of Pharmacy Benefit Managers and Pharmacy Services Administrative Organizations. Regulation 122 defines the roles and responsibilities solely within the purview of pharmacy benefit managers and pharmacy services administrative organizations as required by R.S. 22:1660.9(C).

### **Title 37**

### **INSURANCE**

### **Part XIII. Regulations**

#### **Chapter 185. Regulation Number 122 — Roles and Responsibilities of Pharmacy Benefit Managers and Pharmacy Services Administrative Organizations**

##### **§18501. Purpose**

The purpose of this regulation is to define the roles and responsibilities solely within the purview of pharmacy benefit managers and pharmacy services administrative organizations as required by R.S. 22:1660.9(C).

**AUTHORITY NOTE:** Promulgated in accordance with R.S. 22:11, R.S. 22:1641(8), R.S. 22:1655, R.S. 22:1660.1(B)(1), R.S. 22:1660.8, R.S. 22:1660.9(C) and the Administrative Procedure Act, R.S. 49:950 et seq.

**HISTORICAL NOTE:** Promulgated by the Department of Insurance, Office of the Commissioner, LR

##### **§18503. Applicability and Scope**

A. Regulation 122 shall apply to all pharmacy benefit managers and pharmacy services administrative organizations licensed in Louisiana.

**AUTHORITY NOTE:** Promulgated in accordance with R.S. 22:11, R.S. 22:1641(8), R.S. 22:1655, R.S. 22:1660.1(B)(1), R.S. 22:1660.8, R.S. 22:1660.9(C) and the Administrative Procedure Act, R.S. 49:950 et seq.

**HISTORICAL NOTE:** Promulgated by the Department of Insurance, Office of the Commissioner, LR

##### **§18505. Definitions**

*Pharmacy Benefit Manager*—a person, business, or other entity and any wholly or partially owned or controlled subsidiary of such entity that either directly or through an intermediary manages or administers the prescription drug and device portion of one or more health benefit plans on behalf of a third party, including insurers, plan sponsors, insurance companies, unions, and health maintenance organizations, in accordance with a pharmacy benefit management plan. The management or administration of a plan may include but is not limited to review, processing of drug prior authorization requests, adjudication of appeals and grievances related to the prescription drug benefit, contracting with network pharmacies, and controlling the cost of covered prescription drugs.

*Pharmacy Services Administrative Organization*—an entity that provides a contracted pharmacy with administrative, contracting, or payment services relating to prescription drug benefits.

AUTHORITY NOTE: Promulgated in accordance with R.S. 22:11, R.S. 22:1641(8), R.S. 22:1655, R.S. 22:1660.1(B)(1), R.S. 22:1660.8, R.S. 22:1660.9(C) and the Administrative Procedure Act, R.S. 49:950 et seq.

HISTORICAL NOTE: Promulgated by the Department of Insurance, Office of the Commissioner, LR

#### **§18507. Roles and Responsibilities of Pharmacy Benefit Managers**

A. The roles and responsibilities solely within the purview of pharmacy benefit managers are as follows:

1. administering prescription drug plans for health plan sponsors;
2. formulary and benefit design support and management;
3. establishing reimbursement rates and making payments on behalf of health plan sponsors;
4. establishing and managing pharmacy networks to ensure network adequacy on behalf of health plans;
5. performing drug utilization management;
6. administering disease management and drug adherence programs; and
7. negotiating rebates and discounts from drug manufacturers.

AUTHORITY NOTE: Promulgated in accordance with R.S. 22:11, R.S. 22:1641(8), R.S. 22:1655, R.S. 22:1660.1(B)(1), R.S. 22:1660.8, R.S. 22:1660.9(C) and the Administrative Procedure Act, R.S. 49:950 et seq.

HISTORICAL NOTE: Promulgated by the Department of Insurance, Office of the Commissioner, LR

#### **§18509. Roles and Responsibilities of Pharmacy Services Administrative Organizations**

A. The roles and responsibilities solely within the purview of pharmacy services administrative organizations are as follows:

1. negotiating contracts, drug reimbursement rates, payments, and audit terms on behalf of pharmacy clients with pharmacy benefit managers;
2. billing and collecting payments from payers on behalf of pharmacies;
3. using contractual agreements to develop networks of member pharmacies. These agreements generally authorize pharmacy services administrative organizations to interact with third-party payers and pharmacy benefit managers;
4. negotiating access for pharmacies to networks and patients;
5. facilitating the purchase of prescription drugs and other medical products from drug manufacturers and providing for delivery to pharmacies for dispensing; and
6. assisting pharmacy clients with business strategy, pricing appeals, claims reconciliation, and certification and credentialing requirements.

AUTHORITY NOTE: Promulgated in accordance with R.S. 22:11, R.S. 22:1641(8), R.S. 22:1655, R.S. 22:1660.1(B)(1), R.S. 22:1660.8, R.S. 22:1660.9(C) and the Administrative Procedure Act, R.S. 49:950 et seq.

HISTORICAL NOTE: Promulgated by the Department of Insurance, Office of the Commissioner, LR

#### **§18511. Effective Date**

A. This regulation shall become effective upon final publication in the Louisiana Register.

AUTHORITY NOTE: Promulgated in accordance with R.S. 22:11, R.S. 22:1641(8), R.S. 22:1655, R.S. 22:1660.1(B)(1), R.S. 22:1660.8, R.S. 22:1660.9(C) and the Administrative Procedure Act, R.S. 49:950 et seq.

HISTORICAL NOTE: Promulgated by the Department of Insurance, Office of the Commissioner, LR

### **Family Impact Statement**

1. Describe the Effect of the Proposed Regulation on the Stability of the Family. The proposed regulation should have no measurable impact upon the stability of the family.
2. Describe the Effect of the Proposed Regulation on the Authority and Rights of Parents Regarding the Education and Supervision of their Children. The proposed regulation should have no impact upon the rights and authority of parents regarding the education and supervision of their children.
3. Describe the Effect of the Proposed Regulation on the Functioning of the Family. The proposed regulation should have no direct impact upon the functioning of the family.
4. Describe the Effect of the Proposed Regulation on Family Earnings and Budget. The proposed regulation should have no direct impact upon family earnings and budget.
5. Describe the Effect of the Proposed Regulation on the Behavior and Personal Responsibility of Children. The proposed regulation should have no impact upon the behavior and personal responsibility of children.
6. Describe the Effect of the Proposed Regulation on the Ability of the Family or a Local Government to Perform the Function as Contained in the Rule. The proposed regulation should have no impact upon the ability of the family or a local governmental unit to perform the function as contained in the rule.

### **Poverty Impact Statement**

1. Describe the Effect on Household Income, Assets, and Financial Security. The proposed regulation should have no effect on household income assets and financial security.
2. Describe the Effect on Early Childhood Development and Preschool through Postsecondary Education Development. The proposed regulation should have no effect on early childhood development and preschool through postsecondary education development.
3. Describe the Effect on Employment and Workforce Development. The proposed regulation should have no effect on employment and workforce development.
4. Describe the Effect on Taxes and Tax Credits. The proposed regulation should have no effect on taxes and tax credits.
5. Describe the Effect on Child and Dependent Care, Housing, Health Care, Nutrition, Transportation and Utilities Assistance. The proposed regulation should have no effect on child and dependent care, housing, health care, nutrition, transportation, and utilities assistance.

### **Small Business Analysis**

The impact of the proposed regulation on small businesses as defined in the Regulatory Flexibility Act has been considered. It is estimated that the proposed action is not expected to have a significant adverse impact on small businesses. The agency, consistent with health, safety, environmental and economic welfare factors has considered and, where possible, utilized regulatory methods in the drafting of the proposed regulation that will accomplish the objectives of applicable statutes while minimizing the adverse impact of the proposed regulation on small businesses.

1. Identification and Estimate of the Number of the Small Businesses Subject to the Proposed Rule. The proposed regulation should have no measurable impact upon small businesses.
2. The Projected Reporting, Record Keeping, and Other Administrative Costs Required for Compliance with

the Proposed Rule, Including the Type of Professional Skills Necessary for Preparation of the Report or Record. The proposed regulation should have no measurable impact upon small businesses.

3. A Statement of the Probable Effect on Impacted Small Businesses. The proposed regulation should have no measurable impact upon small businesses.

4. Describe any Less Intrusive or Less Costly Alternative Methods of Achieving the Purpose of the Proposed Rule. The proposed regulation should have no measurable impact on small businesses; therefore, there is no less intrusive or less costly alternative method of achieving the purpose of the proposed regulation.

#### **Provider Impact Statement**

1. Describe the Effect on the Staffing Level Requirements or Qualifications Required to Provide the Same Level of Service. The proposed regulation will have no effect.

2. The Total Direct and Indirect Effect on the Cost to the Provider to Provide the Same Level of Service. The proposed regulation will have no effect.

3. The Overall Effect on the Ability of the Provider to Provide the Same Level of Service. The proposed regulation will have no effect.

#### **Public Comments**

Interested persons who wish to make comments may do so by writing to Jennifer Land, Staff Attorney, Louisiana Department of Insurance, P.O. Box 94214, Baton Rouge, LA 70804-9214, by faxing comments to (225) 342-1632, or electronically at [public@ldi.la.gov](mailto:public@ldi.la.gov). Comments will be accepted through the close of business, 4:30 p.m., April 9, 2022.

James J. Donelon  
Commissioner

#### **Fiscal and Economic Impact Statement**

1. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENTAL UNITS. (Summary)

The proposed rule is not anticipated to result in implementation costs or savings to the state or local governmental units. The proposed rule is promulgated to define roles and responsibilities of pharmacy benefit managers and pharmacy services administrative organizations as required by the LA Pharmacy Services Administrative Organization Licensing Act (R.S. 22:1660.9(C)).

2. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS. (Summary)

The proposed rule will have no impact on state or local governmental revenues.

3. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS, SMALL BUSINESSES, OR NON-GOVERNMENTAL GROUPS. (Summary)

The proposed rule benefits all pharmacy benefit managers and pharmacy services administrative organizations as it gives them guidance as to what their roles and responsibilities are. The proposed rule shall apply to all pharmacy benefit managers and pharmacy services administrative organizations licensed in Louisiana.

4. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT. (Summary)

The proposed rule will have no impact upon competition and employment in the state.